

**Assessment of the USEPA Region 2  
Laboratory Certification Program for Drinking Water  
Draft Report**

**Conducted by the**

**Office of Ground Water and Drinking Water  
Standards and Risk Management Division  
Technical Support Center**

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**Date of Report: September 12, 2016**

## *Introduction*

The Office of Ground Water and Drinking Water (OGWDW) is required to review the EPA regional drinking water certification programs (RLCP) annually including evaluation of the resources and personnel available to carry out the certification program. OGWDW's Technical Support Center (TSC) administers Annual Questionnaires and conducts triennial on-site RLCP Assessments (RLCPAs). The Region 2 RLCPA was conducted March 21 – 24, 2016 at the Region 2 Laboratory in Edison, New Jersey. The assessment team included Carrie Miller from TSC, with contract support from Laurie Potter and Laura Landes of The Cadmus Group. See Attachment A for a copy of the agenda and Attachment B for a list of attendees at the opening and/or exit meetings during the review.

The Manual for the Certification of Laboratories Analyzing Drinking Water<sup>1</sup> (the Certification Manual), Supplement 1<sup>2</sup> and Supplement 2<sup>3</sup> describes a process for the EPA Regions to oversee the certification of the principal state laboratory (PSL), or a PSL network of laboratories, in states that hold primacy by assuring each state has the capability to analyze all regulated drinking water contaminants per federal regulations [40 CFR 142.10(b)(4)]. The PSL laboratories may be certified by the Region, accredited through the National Environmental Laboratory Accreditation Program (NELAP), or recognized through a reciprocity agreement with another SLCP.

If the PSL does not perform analyses for all regulated drinking water contaminants for water systems within the state, the state is required, under terms of primacy, to institute a SLCP to certify commercial and municipal laboratories that analyze drinking water compliance samples [40 CFR 142.10(b)(3)(i)]. The SLCP also may recognize a commercial or municipal laboratory that has been certified or accredited by another state through reciprocity. The EPA regions are also responsible for assessing the adequacy of the state laboratory certification programs [40 CFR 142.10(b)(3)(i)].

In this report, TSC describes their RLCPA of Region 2, including the region's program to assess state laboratory certification programs and to certify PSL. Commendations, findings, and recommendations are summarized.

## **1. Assessment Summary**

### **a. Commendations:**

1. The Region 2 RLCP is well-run with evidence of strong relationships between states, laboratories and the Region 2 staff.
2. Region 2 hosted TSC to conduct both the chemistry and microbiology certification officer courses at the Edison facility in September of 2013. With the assistance of Ms Ringel and the regional laboratory staff, many state COs who hadn't attended refresher training in the past 5 years were able attend and receive the updated information.

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<sup>1</sup> Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition, 2005, EPA 815-R-05-004.

<sup>2</sup> Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement 1 to EPA 815-R-05-004, 2008, EPA 815-F-08-006.

<sup>3</sup> Supplement 2 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement 2 to EPA 815-R-05-004, 2012, EPA 815-F-12-006

3. Region 2 actively participates as a team member in the TNI NELAP-AB evaluations of the New York and New Jersey laboratory accreditation programs. In addition, Ms. Ringel also serves as EPA's liaison to the TNI program, which TSC appreciates. Her positive attitude encourages the TNI states to convey their concerns and request clarifications from EPA. She has a great relationship with the TNI ABs, and as such, they communicate candidly with her. Ms. Ringel has done an exemplary job in following up on specific issues and been instrumental in opening lines of communication that promote improvement in many laboratory certification programs.
4. In the last RLCPA, TSC encouraged Region 2 to follow up and ensure the region's corrective actions (CAs) were implemented by the states to make the SLCPs stronger in the cited areas. It was clear to the TSC assessment team that the Region 2 staff made a conscientious effort to include detailed observations about findings and the corrective actions (CAs) required and documented completion of the CAs.
5. Ms. Ringel has a strong collaborative relationship with the states and territories in Region 2, and has proactively addressed technical and logistical issues. For instance, Region 2 helped to facilitate communication between USVI and PR regarding nitrate analysis. There is inadequate lab capacity in the U.S. Virgin Islands (USVI) and Puerto Rico's has excess capacity for nitrate analysis.
6. The 2012 RLCPA noted procedures for audits of PSLs in the Region 2 Laboratory Certification Program SOP that were not described in detail. The SOP has been updated and implemented by Region 2 to conduct thorough audits.

**b. Findings**

1. None.

**c. Recommendations**

1. TSC encourages Region 2 to continue to keep abreast of the financial crisis occurring in Puerto Rico. The RLCPM noted that funding for the program is at risk and inadequate resources may lead to the loss of the SLCP. Please notify TSC of changes with the fiscal situation in Puerto Rico.
2. The region should expand their SLCPA SOP to further describe:
  - a. the timeline for issuing reports, and tracking CAs;
  - b. how PT results are tracked and the Region's policy for PT failures;
  - c. what/how many records the Region reviews when conducting a SLCPA;
  - d. how states process laboratory downgrades;
  - e. how the region reviews the SLCP organizational chart;
  - f. how the region reviews a list of laboratories certified by the state and the date of the state's most recent audit; and
  - g. how Region 2 reviews the state's fraud detection and reporting procedures.

## **2. EPA Region 2 Laboratory Certification Program Overview**

The Region 2 drinking water program is located in the EPA Region 2 offices in New York City, while the Region 2 drinking water LCP is located at the Region 2 Laboratory (the Environmental Science Center) in Edison, NJ. The Region 2 Certification Authority (CA) has been delegated to Anahita Williamson, Director of the Division of Environmental Science and Assessment. Donna Ringel is the RLCPM. The 4 regional certification officers (COs) are Deborah Kay (Microbiology and Inorganic Chemistry), Kelly Kinder (Microbiology and *Cryptosporidium*), Ness Tirol (Organic and Inorganic Chemistry), and Sumy Cherukara (Organic and Inorganic Chemistry). Their certification responsibility and EPA training status are included in Attachment C. These DW Laboratory Certification Program staff are located at the Regional Laboratory in Edison, NJ.

Region 2 oversees the SLCPs and PSLs/PSL networks for four primacy agencies, including New Jersey, New York, Puerto Rico, and the USVI. Attachment D includes a table showing the number of certified laboratories in each state. Ms. Ringel has been serving as a member of the TNI Accreditation Bodies (ABs) evaluation teams for both NY and NJ. Region 2 intends to continue to participate on these AB evaluation teams. The SLCPs within Region 2 seem to have a sufficient number of COs to adequately audit and certify the number of laboratories. Region 2 currently has enough FTE and travel funding to appropriately operate the LCP.

Attachment E lists the state COs for each Region 2 state, their areas of responsibility, and their EPA training status. Most of the state COs in Region 2 have attended the CO training in the past five years, as recommended in the lab cert manual. Two of the COs in Puerto Rico are overdue to complete refresher training. However, they are not currently conducting laboratory audits, but are available in case a need should arise. Given their status, Region 2 doesn't feel it is a good use of PR's limited funds to require these "back-up" COs to attend refresher training on a regular basis. If these individuals were to become active CO's then Region 2 would recommend they take the EPA training as a refresher.

The region does not have a formal procedure to report fraud for drinking water laboratories. However, Region 2 auditors are all analysts in the fields they audit and aware of opportunities to commit fraud and sensitive to suspicious data. A case in New Jersey led to a large fine, and the region worked with OEI to send notices to RLCPMs that this issue occurred, to ensure any party using data from the laboratory was notified. New Jersey added procedures for fraud detection to their SOP, and state staff participated in training with the Inspector General's office.

## **3. EPA Region 2 State Laboratory Certification Program Assessments**

To meet the Certification Manual's recommendation for yearly review of the state laboratory certification program, EPA Region 2 asks the states to complete the TSC Annual Questionnaire. All states in the region responded fully to the 2015 Annual Questionnaire.

At least triennially, the region performs onsite assessments of the SCLPs, and Region 2 is current with assessments for all SLCPs. The region has developed detailed checklists that include the TNI checklist for interviews and laboratory file reviews. Templates for the checklists are attached to the SOP, and the TSC assessment team found completed checklists with reports in the files. During the SLCPAs, Region 2 reviews files, reports, PT results, SOPs, corrective actions, CO qualifications, training records, management reviews, and the annual QA report. The region

interviews the staff and observes state COs conducting audits, where feasible (not done in Puerto Rico, due to language barriers).

The NJ LCP was evaluated by the TNI AB assessment team in May 2015. Since NJ runs a dual program (meaning the LCP issues both accreditations under the TNI program and certifications using the lab cert manual), Region 2 participates in the TNI program and assesses the certification program. The report from the TNI assessment was issued in June 2015 and included numerous corrective actions. The TNI AB evaluation team recommended provisional accreditation due to numerous repeat findings that had not been resolved. As of March 2016, the TNI AC hadn't voted on the TNI AB evaluation team's recommendation. TNI gave an extension on accreditation until the NELAP-AC has time to vote.

#### **4. Region 2 Principal State Laboratory Audits**

The Region 2 SOP for auditing PSLs is a controlled quality document. The SOP is detailed and covers all elements for conducting an audit as described in the lab cert manual. The SOP clarifies that Region 2 does not conduct independent on-site assessments of a state's contract PSL if that laboratory is NELAP-accredited or certified by another EPA region.

The audit reports for chemistry, microbiology, and radiochemistry laboratories are current for all PSLs certified by the region. Checklists and corrective action plans are in the files. Correspondence between the region and laboratory directors are in most reports. The RLCPM ensures the region gets responses from states to obtain a corrective action plan, and obtains updates on corrective actions.

The region organizes PSL PT results in binders organized by state. PTs are tracked manually in a spreadsheet. Region 2 does not track PT results for commercial laboratories used by USVI. When the RLCPM performs a SLCPA in Puerto Rico and USVI, she confirms that the certification manager has reviewed PT data. The Region 2 PT records were found to be complete.

Region 2 sends letters annually to all the laboratories it certifies. A listing of the laboratory's current certification status for each analyte and method are included. The region does not include an expiration date. Region 2 doesn't issue certification for commercial laboratories accredited through the TNI program, but instead requests documents for the accreditation. Region 2 does review the TNI reports for NYSDOH's PSL prior to making an independent decision to award certification. For example, the region did not certify the New York PSL for method 508A because the lab was not able to meet the method criteria for blank acceptability; however, TNI did accredit the laboratory for this method.

Region 2 participates in the TNI assessments for the NY state laboratories by calling into the exit briefings. Region 2 also reviews the assessment report and tracks PT results for the NYSDOH laboratories. If the RLCPM has concerns about the findings identified in the assessment, she will follow-up with the state principal laboratories and/or the TNI assessors.

The region noted concerns regarding Puerto Rico, because the territory is facing a budget crisis which is affecting the PSL and the LCP. Due to outstanding invoices owed by PR, vendors will no longer supply needed materials, so the PSL may not have equipment/supplies needed to complete analyses. TSC is aware of a plan put together by the US Congress to assist PR in getting their crisis resolved and back on track. TSC encourages Region 2 to monitor this serious situation, and keep TSC staff informed should the situation further deteriorate.



The Region 2 LCP continues to monitor the USVI accounts payable system. Currently USVI program relies on Ocean Systems Laboratory to act as a PSL. Long delays in making payments to Ocean Systems has made the laboratory reluctant to continue in this role. Ocean Systems is the only laboratory on the island, and due to holding time constraints, there is no other laboratory available. Sending samples off-island is not reliable, as sometimes samples will be held up at the airport for customs inspections and exceed the sample holding time. Other times, sample bottles are confiscated and tested for drugs. Region 2 is encouraged to continue working with USVI to maintain the relationship between USVI and Ocean Systems.

## **5. Records Management**

Region 2 SOPs thoroughly describe management of the PT results according to EPA schedule 1035a, and management of the assessments and audits according to EPA Schedule 203. Files dating back at least 10 years are organized by state and contain sections for correspondence, laboratory certificates, SLCPAs, audits, and PTs. Reports from TNI audits are also in the files. Files contain notes, annual questionnaires, SOPs, QA plans from the SLCPs or PSL/PSL network, completed checklists used during on-site visits, reports, copies of correspondence, corrective action plans and progress reports.

The region is supposed to have all electronic records by 2019. QA plans are already electronic. The region noted they need a database to track records retention. The regional records officer consulted the AA of OEI who agreed that SharePoint is not allowable.

## **6. Communication and Technical Assistance**

Routine meetings with states occur approximately every 2-3 years. Regional files contain documentation about the topics discussed and who attended. Although the region has not been hosting annual meetings, routine communication with states via email and phone are documented in the files.

Communication between the RLCP and the Region 2 Drinking Water program is excellent. Copies of assessment and audit reports are sent to the Region 2 drinking water program office. The RLCPM meets with the DW program staff as needed. Communication is documented with meeting minutes and email.

The region provides technical assistance to PSLs upon request. Most requests for assistance are about interpretation of method requirements. Email or other correspondence is maintained to document the technical assistance provided. The RLCPM routinely discusses program issues with TSC and management as issues arise.

## Attachment A

## Agenda: EPA Region 2 Laboratory Certification Program Assessment

<b>Regional Review – EPA Region 2 Laboratory Cert Program</b>			
<b>Final Agenda</b>			
<b>Monday, March 21</b>		<b>Location</b>	<b>Invitees</b>
1:00 PM – 2:00 PM	Opening Conference at Region 2 Laboratory		TSC, Cadmus, Donna Ringel, other R2 staff/management
2:00 PM – 5:00 PM	Region 2 file review		TSC & Cadmus
<b>Tuesday, March 22</b>			
9:00 AM – 12:00 PM	Continue Region 2 file review		TSC & Cadmus
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 5:00 PM	Continue Region 2 file review		TSC & Cadmus
<b>Wednesday, March 23</b>			
9:00 AM – 11:00 AM	Summarize assessment findings		TSC & Cadmus
11:00 AM – 12:00 PM	Exit Meeting/Review of Findings		TSC, Cadmus, Donna Ringel, other R2 staff/management
12:00 PM	Depart for airport		

## Attachment B

## Attendees at Meetings for the March 2016 EPA Region 2 RLCPA

	<b>Participant</b>	<b>Program</b>	<b>Role</b>	<b>Meeting</b>
1.	John S. Kushwara	EPA Region 2	EPA Region 2 Monitoring and Assessment Branch Chief	Opening and exit meetings
2.	Carol Lynes	EPA Region 2	EPA Region 2 Air & Water QA Team Lead	Opening and exit meetings
3.	Donna Ringel	EPA Region 2	EPA Region 2 RLCPM	Opening and exit meetings
4.	Carrie Miller	EPA OGWDW/TSC	TSC Lead Assessor Assessment Team	Opening and exit meetings
5.	Laurie Potter	The Cadmus Group	Contractor Assessment Team member	Opening and exit meetings
6.	Laura Landes	The Cadmus Group	Contractor Assessment Team member	Opening and exit meetings



## Attachment C

## Area of Responsibility and Training Status of Regional Laboratory Certification Program Personnel

Title	Name Office/Branch	Area(s) of Responsibility (Specify Chemistry, Microbiology, Radiochemistry, <i>Cryptosporidium</i> , etc.)	Year Passed EPA CO Training	Year Last Audited EPA CO Training	Year of most recent audit by CO
<b>Regional Administrator</b>	Judith Enck, Regional Administrator	-----	N/A	N/A	
<b>Regional Certification Authority (CA)</b>	Anahita Williamson, Director Division of Environmental Science and Assessment (DESA)	-----	N/A	N/A	
<b>Regional Laboratory Certification Program Manager (RLCPM)</b>	Donna Ringel DESA, Monitoring and Assessment Branch	All	N/A	2013	
<b>Regional Certification Officer (Regional CO)</b>	Deborah Kay Laboratory Branch	Microbiology Inorganic Chemistry	1999 2013	2013 N/A	
<b>Regional Certification Officer (Regional CO)</b>	Kelly Kinder Laboratory Branch	Microbiology <i>Cryptosporidium</i>	2013 2014	N/A N/A	
<b>Regional Certification Officer (Regional CO)</b>	Ness Tirol Laboratory Branch	Organic Chemistry Inorganic Chemistry	2002 2002	2013 2013	
<b>Regional Certification Officer (Regional CO)</b>	Sumy Cherukara Laboratory Branch	Organic Chemistry Inorganic Chemistry	2007 2007	2013 2013	

## Attachment D

## Primacy State Drinking Water Laboratory Certification/Accreditation Programs

## Date of Last Assessment &amp; Number of Laboratories In- and Out-of-State

Primacy State	State Laboratory Certification Program Assessments				Number of Laboratories Certified				
	Agency	Assessor	Date of last SLCPA	Date of last signed report	Chemistry	Microbiology	Radiochemistry	Cryptosporidium	Asbestos
NJ	NJDEP	NELAP Evaluation Team (D. Ringel)	5/2015	6/2015	99 (69)	68 (34)	5 (23)	1 (7)	N/A
NY	NYDOH	NELAP Evaluation Team (D. Ringel)	8/2014	9/2014	47 (66)	113 (46)	4 (17)	2	N/A
PR	PRDOH	D. Ringel	4/2014	6/2014	3 (9)	9 (0)	0 (3)	1 (0)	N/A
VI	VIDPNR	D. Ringel	3/2014	6/2014	0 (2)	2 (1)	0 (1)	0	N/A

## Attachment E

## Area of Responsibility and Training Status of Certification Officers in Primacy States

Name/Affiliation	State	Area(s) of Responsibility (Specify Chemistry, Microbiology, Radiochemistry, <i>Cryptosporidium</i> , etc.)	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Paula Blaze/NJDEP	NJ	Chemistry	1999	2013
		Microbiology	2013	N/A
Amy Bowman/NJDEP	NJ	Chemistry	2004	2013
		Microbiology	2006	2013
Rachel Ellis/NJDEP	NJ	Chemistry	2006	2013
Marc Ferko/NJDEP	NJ	Chemistry	1987	2013
Martin Hackman/NJDEP	NJ	Chemistry	2001	2013
Vas Komanduri/NJDEP	NJ	Chemistry	2001	2013
		Radiochemistry	2006	
Kathy Mance/NJDEP	NJ	Chemistry	2001	2013
		Microbiology	2006	2013
Michele Potter/NJDEP	NJ	Chemistry	2003	2013
		Microbiology	2006	2013
Robert Royce/NJDEP	NJ	Chemistry	1999	2013
		Microbiology	2013	N/A
Ryan Compton/NJDEP	NJ	Chemistry	2015	N/A
Jenna Majchrzak/NJDEP	NJ	Chemistry	2015	N/A
Debra Waller/NJDEP	NJ	Chemistry	2006	2013
		Microbiology	2000	2013
Richard Biega/NYSDOH	NY	Microbiology	2007	2012
		Inorganic Chemistry	2013	N/A
		Organic Chemistry	2013	N/A
Kathie DeNicola/NYSDOH	NY	Microbiology	1986	2011
		Chemistry	1986	2011

Name/Affiliation	State	Area(s) of Responsibility (Specify Chemistry, Microbiology, Radiochemistry, <i>Cryptosporidium</i> , etc.)	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Randy Dersham/NYSDOH	NY	Microbiology	1995	2011
		Chemistry	1995	2011
		Radiochemistry	2006	
Joan Fleser/NYSDOH	NY	Microbiology	2011	N/A
		Organic Chemistry	2010	Past due
		Inorganic Chemistry	2011	N/A
Victoria Pretti/NYSDOH	NY	Microbiology	2008	2012
		Inorganic Chemistry	2008	Past due
Diana Shannon/NYSDOH	NY	Chemistry	2011	2012
Anne Sheehan/NYSDOH	NY	Microbiology	2003	2014
		Chemistry	2003	2014
		<i>Cryptosporidium</i>	2015	N/A
Gale Warren/NYSDOH	NY	Microbiology	2008	2012
		Chemistry	2008	2012
		<i>Cryptosporidium</i>	2015	N/A
Thomas Zgrodnik/NYSDOH	NY	Microbiology	2005	2011
		Chemistry	2005	2011
		Radiochemistry	2006	
Nadalie Joseph/VIDPNR	VI	Microbiology	2007	Past due
Nancy Sanchez/PRDOH	PR	Microbiology	2009	2014
		<i>Cryptosporidium</i>	2011	N/A
Mariely Rivera	PR	Chemistry	2015	N/A
		Radiochemistry	2015	
Norma Rivera	PR	Microbiology	2007	Past due
Gissel Rodriguez	PR	Chemistry	2009	Past due